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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,320	11/23/2001	Francine Goulet	216483US6	2528

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EXAMINER

LANDREM, KAMRIN R

ART UNIT PAPER NUMBER

3738

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,320

Applicant(s)

GOULET ET AL.

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-50 is/are pending in the application.
- 4a) Of the above claim(s) 25-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-24 and 45-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/19/04 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein in view of Silver et al (USPN 5,171,273) and Campbell et al (USPN 5,067,962).

Goldstein, as discussed in Paper No. 14, discloses an implant for connective tissue substitution (3:14-24) and methods to prepare the implant that comprises a matrix layer that is seeded with allogenic or autologous cells (9:34-67) and a pharmaceutically effective amount of a biologically active molecule (10:10-47). The matrix layer is of sufficient thickness to allow for colonization of cells after implantation. The connective tissue can be used for skin, tendon, ligament, muscle, bone and cardiovascular structures (4:18-23). The implant can be used in

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either humans or animals. The matrix may contain glycosaminoglycan (8:40+) and may also be populated with fibroblast (9:55-66) after implantation. Goldstein discloses all of the claimed elements except for the particulars pertaining to treating the implant before implantation and the specific implant structure. Campbell et al teaches a bioprosthetic ligament for replacing a damaged anterior cruciate ligament (2:48-60) comprising a pair of natural porous bone anchors 23,24 joined together at their proximal ends by a natural support filament 16 that enables the surgeon to closely replicate the natural attachment structures being replaced. Silver et al also discloses a synthetic collagen implant that undergoes cross-linking by way of a process of severe dehydration (8:54-64) prior to implantation to create a high strength collagen graft that is useful as an implant for the repair of damaged tendons and ligaments (3:53-60). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to modified the implant disclosed by Goldstein to include the dehydration step taught by Silver while having the structure of the bioprosthetic ligament taught by Campbell in order to provide the patient with a natural replacement that more closely replicates their own natural attachment structures with cross-linked collagen fibers that provide a stronger matrix.

Claims 8, 17, 18, 19, 20, 21, 22, 23, 24, 45, 46, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein as modified by Silver and Campbell as applied to claims 1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 49 and 50 above, and further in view of Altman et al (USPN 6,287,340).

As discussed above, Goldstein as modified by Silver and Campbell discloses an implant for connective tissue substitution comprising a pair of bone anchors joined at their proximal ends by a support filament that is coated by a matrix layer of sufficient thickness to allow for

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colonization by a cell. Goldstein as modified by Silver and Campbell discloses all of the claimed elements except for the particulars pertaining to the collagen gel matrix. Altman et al teaches the formation of a bioengineered anterior cruciate ligament with a matrix material composed of collagen gel (2:19-39) which allows cells to adhere to the matrix and grow (2:25) by a process is likely to increase the efficiency of production of the bioengineered anterior cruciate ligament replacement (4:50-67). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the implant as disclosed by Goldstein and modified by Silver and Campbell by using a collagen gel as taught by Altman to allow cells to adhere and regeneration within the matrix and by a process with increased efficiency.

Response to Arguments

Applicant's arguments with respect to claims 1 and 16 have been considered but are moot in view of the new ground(s) of rejection. The Examiner has provided a teaching to overcome the applicant's arguments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem
Examiner
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krl


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